2022 Michigan Newborn Screening Program Annual Report

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Executive Summary

The Newborn Screening (NBS) Annual Report provides an overview of the Michigan NBS Program, screening performance metrics and quality assurance information. Since the program began in 1965 with screening for phenylketonuria, more than 50 disorders have been added to the screening panel. Through 2022, more than 7.7 million infants have been screened with more than 8,000 diagnosed with diseases included in the NBS blood spot panel. Of the 100,176 infants screened in 2022, the vast majority were Michigan residents and 322 (0.3%) were diagnosed with a disease. Overall, one infant out of 311 screened was diagnosed with one of the disorders included in the NBS panel (see Page 5 for list of disorders).

Developments occurring in 2022:

Michigan continued to disseminate findings at both the state and national level:

• The findings from different studies and analyses related to NBS were presented at the Association of Public Health Laboratories (APHL) Newborn Screening and Genetic Testing Symposium.

Michigan continued to conduct NBS-related trainings:

- The NBS Follow-up Program held two virtual educational conference for hospital staff. A total of 136 people, representing 53 birth hospital and 18 Michigan homebirth attendants, attended.
- The NBS Follow-up Program conducted 25 virtual hospital site visits.

NBS follow-up staff presented or participated as an exhibitor at numerous educational events including:

- Six MDHHS Virtual Baby Fairs.
- 2022 Maternal Infant Health Submit.
- · Medical Genetics Resident Presentation.
- Wayne Pediatrics Virtual Lecture series.
- Sparrow Pediatric Grand Rounds.

NBS laboratory personnel and follow-up staff continued to serve on national NBS committees, including:

- Education and Training workgroup for the Advisory Committee on Heritable Disorders in Newborns and Children.
- The Clinical Laboratory Standards Institute Document Development Committee.
- Health Information Technology (HIT) Association of Public Health Laboratories (APHL) work group.
- Quality assurance/Quality control APHL Subcommittee work group.

Continuing work:

• The Michigan NBS Program began screening for Guanidinoacetate methyltransferase (GAMT) deficiency in September 2022. More information about GAMT deficiency can be found https://example.com/here/.

Disorders included on the Newborn Screening Blood Spot Panel, 2022

Amino Acid Disorders	Organic Acid Disorders
1. Argininemia	30. 2-Methyl-3-hydroxy butyric aciduria
2. Argininosuccinic acidemia	31. 2-Methylbutyryl-CoA dehydrogenase deficiency
3. Citrullinemia	32. 3-Hydroxy 3-methylglutaric aciduria
4. Citrullinemia Type II	33. 3-Methylcrotonyl-CoA carboxylase deficiency
5. Homocystinuria	34. 3-Methylglutaconic aciduria
6. Hypermethioninemia	35. Beta-ketothiolase deficiency
7. Maple syrup urine disease	36. Glutaric acidemia Type I
8. Phenylketonuria	37. Isovaleric acidemia
9. Benign hyperphenylalaninemia defect	38. Methylmalonic acidemia (Cbl A, B)
10. Biopterin cofactor biosynthesis defect	39. Methylmalonic acidemia (Cbl C, D)
11. Biopterin cofactor regeneration defect	40. Methylmalonic acidemia (mutase deficiency)
12. Tyrosinemia Type I	41. Multiple carboxylase deficiency
13. Tyrosinemia Type II	42. Propionic acidemia
14. Tyrosinemia Type III	Hemoglobinopathies
Fatty Acid Oxidation Disorders	43. S/Beta thalassemia
15. Carnitine acylcarnitine translocase deficiency	44. S/C disease
16. Carnitine palmitoyltransferase I deficiency	45. Sickle cell anemia
17. Carnitine palmitoyltransferase II deficiency	46. Variant hemoglobinopathies
18. Carnitine uptake defect	47. Hemoglobin H disease
19. Dienoyl-CoA reductase deficiency	Endocrine Disorders
20. Glutaric acidemia Type II	48. Congenital adrenal hyperplasia
21. Long-chain L-3-hydroxyl acyl-CoA dehydrogenase deficiency	49. Congenital hypothyroidism
22. Medium/short-chain L-3-hydroxyl acyl-CoA dehydrogenase deficiency	Other Disorders
23. Medium-chain acyl-CoA dehydrogenase deficiency	50. Biotinidase deficiency
24. Medium-chain ketoacyl-CoA thiolase deficiency	51. Galactosemia
26. Trifunctional protein deficiency	52. Cystic fibrosis
27. Very long-chain acyl-CoA dehydrogenase deficiency	53. Severe combined immunodeficiency
Lysosomal Storage Disorders	54. T-cell related lymphocyte deficiencies
28. Pompe Disease	55. X-linked adrenoleukodystrophy
29. Mucopolysaccharidosis I	56. Spinal muscular atrophy

Notes: Highlighted disorders have never been detected in Michigan through NBS. The following disorders are reported together because the same analyte(s) is used for screening: #3/4, #5/#6, #8-11, #13/#14, #15/#17, #21/#26, #31/#37, #32-34/#41, #38-#40/42, and #30/#35.

57. Guanidinoacetate methyltransferase (GAMT) deficiency

Indicator	Description
Newborns (N)	The total number of screened live births among in-state residents.
Total + (% NICU)	Total number of positive screens among in-state residents (the percentage of infants with positive screens who were admitted to the NICU among all infants with positive screens).
Positive	Screening value exceeds cutoff.
Strong +	Strong positive screen (in most cases considered a medical emergency and referred immediately for diagnostic testing).
Borderline +	Borderline positive screen (not a medical emergency and repeat screen requested).
Confirmed +	A diagnosis of a disorder that has been confirmed.
False +	A positive screen that is not confirmed as a case of a disease included in the NBS panel.
Detection Rate	The number of infants having a confirmed disorder out of the total number of infants screened, depicted as a ratio. One case per 'X' number of infants screened depicted as 1: 'X'.
FPR	False positive rate: the number of infants with false positive screens divided by the total number of infants screened, expressed as a percentage.
PPV	Positive predictive value: the number of infants confirmed with a disorder divided by the number of infants having positive screens, expressed as a percentage.

Screening performance metrics included in subsequent tables are shown above. These indicators are commonly used to assess the performance of screening tests and allow for comparisons both over time and with other screening programs. Ideal screening tests have a high positive predictive value (perfect = 100%) and a low false positive rate (perfect = 0%). A perfect screening test correctly identifies all cases of a disorder with no false positives. Detection rates, the total number of cases identified out of the total number of newborns screened, are based on the total number of screens for in-state residents. Cases are defined as newborns identified with disorders via NBS. Maternal disorders and carriers identified by NBS are not included as confirmed cases in the performance metrics, though they are presented in this report.

Screened Newborns

The Michigan NBS Program screened 98.9% of the live births occurring in Michigan in 2022, as determined by the linkage of NBS records to preliminary live births records received from the Vital Records & Health Data Development Section and follow-up of unmatched records (Figure 1). Of the 101,386 live births that occurred in 2022, 287 were listed as deceased on their birth certificate. Many of these infants are not screened due to their short life spans, so they are excluded from the linkage calculations. Of the 101,099 remaining live births, the linkage algorithm successfully matched newborn screens for 99,585 infants (98.5%). The 1,514 unmatched records were sent to NBS follow-up program technicians for further investigation. This more in-depth follow-up revealed that 404 (26.7%) of the unmatched records were screened in Michigan. For these infants, the linkage algorithm failed to create the match for a variety of reasons, including data recording errors, data entry errors, name changes due to adoptions and misplaced or missed screens that were not completed until after follow-up by NBS follow-up program staff.

Overall, 1,110 infants (1.1%) with a Michigan birth certificate were not screened in Michigan. Of those 1,110 infants, 160 were screened out-of-state. Of the remaining 950 infants, 596 were not screened due to parents not permitting the collection of the screen, 34 were not screened due to palliative care or a death after the birth certificate was filed, two were screened at a private lab, six were transferred out of state before screening, and the reason the screen was not completed is unknown for 312 infants. For all infants without a newborn screen, NBS follow-up staff either contact the NBS coordinator for hospital births or send a parental notification and midwife notification letter for home births.

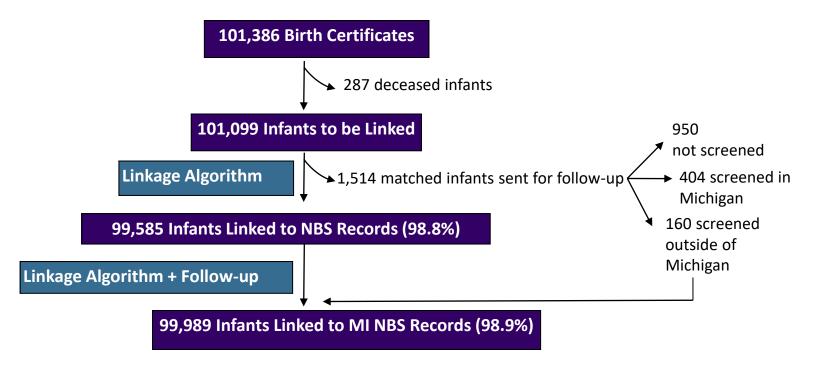


Figure 1. Newborn Screening and Live Births Records Linkage, Michigan, 2022

Screening Outcome Information

In the following subsections, outcome information is provided for the disorders included in the NBS panel in 2022. The total numbers of cases detected both in and through 2022 are presented along with screening performance metrics.

Table 1 reports the cumulative detection rate of disorders identified via NBS by classification both in and through 2022. The metabolic disorders detected by Tandem Mass Spectrometry (MS/MS) are grouped by category (amino acid, organic acid and fatty acid oxidation disorders). Two metabolic disorders, galactosemia and biotinidase deficiency, are detectable by enzyme assay screening rather than MS/MS and are listed separately. The galactosemia cumulative detection rate includes both duarte compound heterozygotes (D/G) and classic galactosemia (G/G). However, only D/G cases that have been detected since 2004, the year that the Children's Hospital of Michigan Metabolic Clinic (CHMMC) began short-term treatment of this disorder, are included in the cumulative detection rate. Similarly, the biotinidase deficiency cumulative detection rate includes both partial and profound biotinidase deficiency. Treatment of partial biotinidase deficiency did not begin until 2000.

Table 1: Disorders Identified in Newborns via Newborn Screening, Michigan, 1965-2022

Disorder Type	Cases in 2022 (N)	Cases Through 2022 (N)	Detection Rate (1:X) ¹
Galactosemia (1985)	6	234	20,415
Biotinidase Deficiencies (1987)	14	402	11,205
Amino Acid Disorders (1965)	8	824	20,075
Organic Acid Disorders (2005)	5	121	16,735
Fatty Acid Oxidation Disorders (2003)	12	317	7,210
Congenital Hypothyroidism (1977)	144	2,994	1,505
Congenital Adrenal Hyperplasia (1993)	5	190	19,104
Sickle Cell Disease (1987)	49	2,257	1,996
Hemoglobin H Disease (2012)	1	26	45,624
Cystic Fibrosis (2007)	15	386	4,344
Primary Immunodeficiencies (2011)	38	188	6,906
Lysosomal Storage Disorders (2017)	9	44	12,830
X-Linked Adrenoleukodystrophy (2019)	4	9	36,686
Spinal Muscular Atrophy (2020)	12	33	9,736
Total	322	8,025	-

¹Data interpretation: The detection rate reflects the number of infants screened per confirmed case. For example, one in every 20,415 infants screened for galactosemia between 1985 and 2022 have the disorder.

Table 2 reports screening performance metrics for all disorders in 2022. Screening performance metrics include the detection rate, false positive rate (FPR), and positive predictive value (PPV).

Table 2: Screening Results and Performance Metrics, Michigan, 2022, Screened N=99,836

Disorder Type	Positives (N)	Confirmed cases (N)	Detection Rate (1:X) ¹	FPR (%)	PPV (%)
Galactosemia	11	6	16,639	0.01	54.5
Biotinidase Deficiencies	55	14	7,131	0.04	25.5
Amino Acid Disorders	29	8	12,480	0.02	27.6
Organic Acid Disorders	20	5	19,967	0.02	25.0
Fatty Acid Oxidation Disorders	90	12	8,320	0.08	13.3
Congenital Hypothyroidism	2,016	144	693	1.88	7.1
Congenital Adrenal Hyperplasia ²	109	5	19,967	0.10	4.6
Sickle Cell Disease	64	49	2,037	0.02	76.6
Hemoglobin H Disease	12	1	99,836	0.01	8.3
Cystic Fibrosis ³	309	15	6,656	0.29	4.9
Primary Immunodeficiencies	90	38	2,627	0.05	42.2
Lysosomal Storage Disorders	23	9	11,093	0.01	39.1
X-Linked Adrenoleukodystrophy	17	4	24,959	0.01	23.5
Spinal Muscular Atrophy	12	12	8,320	0.00	100.0

¹ Data interpretation: The detection rate reflects the number of infants screened per confirmed case. For example, one in every 16,639 infants screened in 2022 for galactosemia have the disorder.

A breakdown of amino acid disorders can be found in Table 3, a breakdown of organic acid disorders can be found in Table 4, a breakdown of fatty acid oxidation disorders can be found in Table 5, a breakdown of sickle cell disorders can be found in Table 6 and a breakdown of lysosomal storage disorders can be found in Table 7.

For some disorders, infants receive further classification upon diagnosis. Of the six cases of galactosemia, four confirmed with classic galactosemia and two confirmed with duarte galactosemia. Of the 14 cases that confirmed with biotinidase deficiency, 13 confirmed with partial biotinidase deficiency and one confirmed with profound biotinidase deficiency. Six cases of congenital adrenal hyperplasia confirmed, five were salt wasting and one was a non-salt wasting cases. Of the 38 newborns with primary immunodeficiencies, one confirmed with severe combined immunodeficiency (SCID), 11 confirmed with syndromes of T-cell impairment, and 26 confirmed with T-cell lymphopenias. No cases of adenosine deaminase (ADA) SCID were detected in 2022.

² One congenital adrenal hyperplasia case was not detected by NBS; this case is not included in case counts.

³ Fourteen CF related metabolic syndrome (CRMS) cases were also detected through screening; these cases are not included in case counts.

Table 3: Amino Acid Disorders Screening Performance Metrics, Michigan, 2022, Screened N= 99,836

Disorder	Positives (N)	Confirmed Cases (N)	Detection Rate (1:X) ¹	FPR (%)	PPV (%)
Phenylketonuria (PKU) Total	10	6	16,639	0.004	60.0
Medically treated PKU	-	3	33,279	-	-
Hyperphenylalaninemia	-	3	33,279	-	-
Citrullinemia (CIT)/CIT II	4	0	-	0.004	0.0
Tyrosinemia I (TYR I)	3	1	99,836	0.002	33.3
Tyrosinemia II/III (TYR II/III)	5	0	-	0.005	0.0
Maple Syrup Urine Disease (MSUD)	4	1	99,836	0.003	25.0
Homocystinuria (HCY)	1	0	-	0.001	0.0
Argininemia	2	0	-	0.002	0.0

¹ Data interpretation: The detection rate reflects the number of infants screened per confirmed case. For example, one in every 16,639 infants screened for phenylketonuria in 2022 have the disorder.

Table 4: Organic Acid Disorders Detected Screening Performance Metrics, Michigan, 2022, N= 99,836

Disorder Type		Confirmed	Detection	FPR	PPV
		cases (N)	Rate (1:X) ¹	(%)	(%)
3-Methylcrotonyl-CoA Carboxylase Deficiency (3MCC)	4	0	-	0.004	0.0
Proprionic Acidemia/Methylmalonic acidemia (PA/MMA)	10	2	49,918	0.008	20.0
2-Methyl-3-hydroxy butyric aciduria/Isovaleric acidemia (2MBG/IVA)	4	3	33,279	0.001	75.0
Dienoyl-CoA reductase deficiency (DERED)	2	0	-	0.002	0.0

¹ Data interpretation: The detection rate reflects the number of infants screened per confirmed case. For example, one in every 48,918 infants screened for PA/MMA in 2022 have the disorder.

Table 5: Fatty Acid Oxidation Disorders Screening Performance Metrics, Michigan, 2022, N= 99,836

Disorder Type		Confirmed cases (N)	Detection Rate (1:X) ¹	FPR (%)	PPV (%)
Carnitine uptake defect (CUD)	67	1	99,836	0.066	1.5
Carnitine palmitoyltransferase II deficiency (CPT II)	2	1	99,836	0.001	50.0
Glutaric acidemia Type II (GA II)	1	0	-	0.001	0.0
Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)	10	9	11,093	0.001	90.0
Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)	5	1	99,836	0.004	20.0
Long-chain L-3-hydroxyl acyl-CoA dehydrogenase deficiency (LCHAD)	5	0	-	0.005	0.0

¹ Data interpretation: The detection rate reflects the number of infants screened per confirmed case. For example, one in every 99,836 infants screened for CUD in 2022 have the disorder.

Table 6. Hemoglobinopathy Screening Performance Metrics, Michigan, 2022, N= 99,836

Disorder	Total Confirmed Cases	Total Confirmed Cases among Black Populations	Detection Rate (1:X)	Detection Rate among Black Populations (1:X)
Sickle Cell Anemia	29	24	3,443	699
SC Disease	19	16	5,255	1,048
Sickle β thalassemia	1	1	99,836	16,771
Total	49	41	2,037	409

¹ Data interpretation: The detection rate reflects the number of infants screened per confirmed case. For example, one in every 2,037 infants screened for sickle cell disease in 2022 have the disorder.

Note: One case of Hemoglobin C was also detected.

Table 7: Lysosomal Storage Disorders, Screening Performance Metrics, Michigan, 2022, N= 99,836

Disorder	Positives (N)	Confirmed cases (N)	Detection Rate (1:X) ¹	FPR (%)	PPV (%)
Pompe Disease	12	9	11,093	0.003	75.0
Mucopolysaccharidosis I (MPS1)	13	0	-	0.013	0.0

¹ Data interpretation: The detection rate reflects the number of infants screened per confirmed case. For example, one in every 11,093 infants screened for pompe disease in 2022 have the disorder.

² Data interpretation: The detection rate among Black populations reflects the number of Black infants screened per confirmed case. In 2022, there were 16,771 Black infants screened. For example, one in every 409 Black infants screened for sickle cell disease in 2022 have the disorder.

Carriers and Maternal Disorders

Although the overarching goal of NBS is to detect disorders in newborns, carriers and maternal disorders are also identified. For disorders in the NBS panel, carriers have one normal gene and one mutated gene and typically do not display any clinical symptoms. On a routine basis, the NBS Follow-up Program refers all newborns with positive screens to the appropriate medical management coordinating center that will follow up to determine the final diagnosis: no disease, disease, carrier, or maternal disorder. NBS will only detect carriers or maternal disorders following an abnormal screen. Thus, NBS will not identify all carriers or all maternal disorders.

In 2022, a total of 2,670 infants were identified as carriers of a disease included in the NBS panel, following an abnormal screen (Table 8). Besides confirmatory diagnostic testing for infants, medical management centers also offer diagnostic testing for mothers. Since mothers may have the disease rather than the infant, they could possibly be identified through NBS for a few disorders. No maternal cases were detected in 2022.

Table 8: Carriers Identified from Newborn Screening, Michigan, 2022

Disorder	Carriers (N)
Hemoglobin Traits	2,393
Cystic fibrosis (CF)	271
Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)	2
Mucopolysaccharidosis I (MPS1)	1
Pompe Disease	1
Long-chain L-3-hydroxyl acyl-CoA dehydrogenase deficiency (LCHAD)	1
Carnitine uptake defect (CUD)	1

Time to Treatment

Turn-around time in NBS refers to the time from birth to initiation of treatment. The target turn-around time for initiating treatment for the early-onset life-threatening disorders (CAH, galactosemia and disorders detected by MS/MS) is no later than the seventh day of life. The goals for other disorders vary. Table 9 reports the time to treatment for disorders other than hemoglobinopathies, cystic fibrosis, X-Linked adrenoleukodystrophy, and SCID. As indicated in Table 9, time to treatment ranged from zero to 105 days among all disorders. Since borderline positive screens require one or more retests before being referred for confirmatory testing, congenital hypothyroidism (CH) is presented separately by initial screening result (strong or borderline) in the table.

Table 9: Time to Treatment, Michigan, 2022

Disorder		Treated on 1-7 days of Life	Treated on 8-14 days of life	Treated >14 days of life	Treatment Time Range (days)
Spinal Muscular Atrophy (SMA)	12			12	14-75
Classic Galactosemia	4	4			0-3
Biotinidase Profound	1	1			5
Biotinidase Partial	13	9	2	2	4-16
Medically treated (PKU)	3	2	1		7-9
Tyrosinemia I (TYR I)	1	1			4
Maple Syrup Urine Disease (MSUD)	1	1			7
Proprionic Acidemia (PA)	2	1	1		3-24
2-Methyl-3-hydroxy butyric aciduria/Isovaleric acidemia (2MBG/IVA)	3	3			4-5
Carnitine palmitoyltransferase II deficiency (CPT II)	1	1			2
Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)	9	8		1	3-48
Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)	1	1			3
Carnitine uptake defect (CUD)	1	1			3
Pompe Disease- classic infantile onset	3		3		9-13
Congenital Hypothyroidism (CH)– Strong	69	31	24	14	4-41
Congenital Hypothyroidism (CH)– Borderline	75	5	15	55	5-105
Congenital Adrenal Hyperplasias (CAH)— Salt Wasting	4	3	1		2-8
Total	203	72	47	84	0-105

Table 10 reports the time to treatment among newborns with hemoglobinopathies. The target is to initiate penicillin prophylaxis by four months of life (120 days).

Table 10: Time to Penicillin Initiation for Sickle Cell Disorders, Michigan, 2022

Disorder	Total Confirmed	Penicillin Prophylaxis Initiated < 120 days	Penicillin Prophylaxis Initiated 120-149 days	Penicillin Prophylaxis Initiated > 150 days	
Sickle cell disorder ¹	49	41	2	2	

¹ Penicillin initiation date is unknow for 4 infants.

NBS Performance measures

The Michigan NBS Program prepares quarterly hospital reports to evaluate how hospital are performing on key NBS indicators and highlight areas for improvement. During 2022, the hospital quarterly reports included six indicators related to blood spot screening. Those indicators are displayed below:

Late Screens:	Less than 2% of screens collected greater than 36 hours after birth.		
Appropriate Day:	Greater than 90% of screens arrive in state laboratory on or before the appropriate day.		
Unsatisfactory Screens:	Less than 1% of screens are unsatisfactory.		
NBS Card Number:	Greater than 95% of electronic birth certificates have the correct NBS card number recorded.		
Returned BioTrust Consent Forms	At least 90% of specimens have a returned consent form that is completed appropriately.		
NBS card with incorrect dates/times:	Less than 1% of specimen have errors in their birth date/ time and/or collection date/time on the NBS card.		

Table 11 lists the statistics for each performance measure and whether the goal was met by nursery type. Nursery type includes regular baby nurseries, the neonatal intensive care and special care nurseries (NICU/SCN), and non-hospital births.

Table 11: Measures for Newborn Screening, by Nursery Type, Michigan, 2022

Measure by Nursery Type		%	Met Goal?
Late Screens: Regular	359	0.4	Yes
Late Screens: NICU/SCN	109	1.0	Yes
Late Screens: Non-hospital	833	55.1	No
Appropriate Day: Regular		92.2	Yes
Appropriate Day: NICU/SCN		87.7	No
Appropriate Day: Non-hospital ¹		NA	NA
Unsatisfactory Screens: Regular	1,407	1.6	No
Unsatisfactory Screens: NICU/SCN	265	2.4	No
Unsatisfactory Screens: Non-hospital		3.0	No
NBS Card Number: Regular		96.1	Yes
NBS Card Number: NICU/SCN ²		87.8	N/A
NBS Card Number: Non-hospital		80.6	No
Returned BioTrust Consent Forms: Regular		88.7	Yes
Returned BioTrust Consent Forms: NICU/SCN		64.8	No
Returned BioTrust Consent Forms: Non-hospital		76.8	No
NBS card with incorrect dates/times: Regular		2.6	No
NBS card with incorrect dates/times: NICU/SCN		3.2	No
NBS card with incorrect dates/times: Non-hospital		6.3	No

¹Receipt by appropriate day is not calculated for non-hospital births because they do not have a designated courier pick-up time for each day like birthing facilities have.

²Recording of NBS card number is not a performance measure for NICUs since the birth hospital is asked to draw the NBS specimen before transferring the infant to the NICU.

Conclusion

NBS is a critical public health program that protects the lives of our state's newest residents. The NBS Laboratory screened 100,176 infants born in 2022, and the NBS Follow-up Program tracked approximately 7,700 positive, isolated elevation, unsatisfactory, early, and transfused specimens. Newborns with strong positive screening results were immediately referred to the appropriate NBS follow-up coordinating center for evaluation. A total of 322 newborns were identified with a disorder by NBS in 2022, as well as 2,670 carriers. Since blood spot screening began in Michigan in 1965, 8,025 newborns have been diagnosed and treated. We are continuing to both expand and refine the NBS Program in order to better protect the health of infants born in Michigan.

The Michigan Department of Health and Human Services (MDHHS) does not discriminate against any individual or group on the basis of race, national origin, color, sex, disability, religion, age, height, weight, familial status, partisan considerations, or genetic information. Sex-based discrimination includes, but is not limited to, discrimination based on sexual orientation, gender identity, gender expression, sex characteristics, and pregnancy.